SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

name of product：Ciprofloxacin Lactate Eye Drops

strength：8ml:24mg

pharmaceutical form：Eye Drops

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Ciprofloxacin Lactate(ciprofloxacin counted)	24mg
Sodium chloride	64mg
Disodium edetate	0.8mg
Ethylparaben	4mg
Lactic acid	0.00136ml
Water for Injection	q.s.to 8ml

3. PHARMACEUTICAL FORM

Drops

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used for external eye infections caused by sensitive bacteria (such as conjunctivitis, etc.)

4.2 Posology and method of administration

Drop in the eyelid, 1~2 drops, 3~5 times a day.

4.3 Contraindications

Patients who are allergic to this product and quinolones are prohibited.

4.4 Special warnings and special precautions for use

1. only for eye drops.

2.In case of allergic symptoms such as rash or other serious adverse reactions during use, the drug should be stopped immediately.

4.5 Interaction with other FPPs and other forms of interaction

After long-term use and local absorption, it can produce the same drug interactions as systemic drugs, such as increasing the blood concentration of theophylline, cyclosporine, probenecid and other drugs, enhancing the anticoagulant effect of warfarin, and interfering with the metabolism of caffeine.

4.6 Pregnancy and lactation

Animal experiments have not proved that quinolones have teratogenic effect, but there is no clear

conclusion on the study of pregnant women's medication. In view of the fact that this medicine can cause juvenile animal joint diseases, pregnant and lactating women should use it with caution.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Occasionally, there are symptoms of local transient stimulation. It can cause local burns and foreign body sensation. In addition, eyelid edema, tears, photophobia, vision loss and allergic reaction are rare.

4.9 Overdose

This test has not been conducted and there are no reliable references.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

This product has broad-spectrum antibacterial activity, especially against aerobic gram-negative bacilli, and has good antibacterial activity in vitro against most of the following bacteria: Enterobacteriaceae, including Citrobacter, Enterobacter cloacae, Enterobacteraerogenes, Escherichia coli, Klebsiella, Proteus, Salmonella, Shigella, Vibrio, Yersinia, etc. It also has antibacterial activity against multi-drug resistant bacteria. Penicillin-resistant Neisseria gonorrhoeae, enzyme-producing influenza and Moraxella have high antibacterial activity. It has antibacterial effect on most strains of pseudounicellular bacteria such as pseudounicellular bacteria aeruginosa. This product has antibacterial activity against methicillin-sensitive staphylococcus, but only moderate antibacterial activity against streptococcus pneumoniae, hemolytic streptococcus and enterococcus faecalis. It has good antimicrobial activity against Chlamydia trachomatis, Mycoplasma and Legionella, and also has antibacterial activity against Mycobacterium tuberculosis and atypical mycobacteria. Poor antibacterial activity against anaerobic bacteria.

Ciprofloxacin, as a bactericide, inhibits DNA synthesis and replication by acting on subunit A of helicases of bacterial DNA, resulting in bacterial death.

5.2 Pharmacokinetic properties

This product is for local use, only a small amount of absorption. According to literature reports, the peak blood drug concentration (Cmax) after repeated eye drops is less than 5ng/ml, and the average concentration is generally less than 2.5ng/ml.

5.3 Preclinical safety data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Sodium chloride	64mg
Disodium edetate	0.8mg
Ethylparaben	4mg
Lactic acid	0.00136ml
Water for Injection	q.s.to 8ml

6.2 Incompatibilities

Patients who are allergic to this product and quinolones are prohibited.

6.3 Shelf life

24months

6.4 Special precautions for storage

Keep in an airtight condition, protected from light.

6.5 Nature and contents of container

Plastic eye drops bottle, 8ml/ piece/box

6.6 Instructions for use and handling

Drop in the eyelid, 1~2 drops at a time, 3~5 times a day.

7. MARKETING AUTHORISATION HOLDER

Jiangsu Farever Pharmaceutical Co., Ltd.

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

JIA/CHI/492

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/08/2018

10. DATE OF REVISION OF THE TEXT

March 19th, 2022